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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,426	04/12/2004	Naweed Muhammad	524522001300	4034

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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/823,426	MUHAMMAD ET AL.	
	Examiner	Art Unit	
	MICAH-PAUL YOUNG	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 May 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,7,9-11,85,86,88-90,93,95,97-105 and 122-145* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,7,9-11,85,86,88-90,93,95,97-105 and 122-145* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/19/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 132 and 144 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification has support for up to 6 months of pain relief, while the claims recite at least six months, effectively claiming no upper limit to the pain relief. The specification does not support an unlimited upper limit on the pain relief. Correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 7, 9, 10, 11, 85, 86, 88-90, 93, 95, 97-105, and 122-145 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of O'Neil et al (EP 0 347 000 hereafter '000) in view of LaHann et al (USPN 4,546,112 hereafter '112) in further view of Beerse et al (USPN 5,968,539 hereafter '539).

The '000 patent teaches a topical formulation comprising a TPV1 agonist and various excipients that is applied to herpes infected skin in humans (abstract, claims). The agonist is a vanilloid or synthetic capsaicin (8-methyl-N-vanillyl-6-nonenamide) and is incorporated in topical formulations such as creams, salves, solutions and sprays (pg. 8, lin. 50-58; pg 9, lin. line -pg 12, lin. 14). Capsaicin is a known analgesic (pg. 9, lin. 4-6). Capsaicin comprises methylnonenoic acid so any formulation comprising capsaicin would inherently comprise the acid. The formulations are applied to an infected area of the skin or mucosa, where the formulation has a vanilloid concentration from 1-20 mg/sq cm, with at least 0.1-2 mg/kg of body weight (pg 12, lin. 19-44). The preparations comprise carriers that are present in concentration from 95-99.5 % (pg. 9, lin. 24-29). The formulations include lotions with comprise water, oil and various emulsifying agents forming microemulsion comprising from 0.001to about 5% of the active agent (pg. 9, lin. 50-55). The formulations comprise from 0.001 to about 5% of the vanilloid, with the remainder as an emollient solvent system comprising penetration enhancers and supporting excipients (pg. 11, lin. 21-25). The penetration enhancers include propylene glycol, ethanol isopropanol and mixtures thereof (pg. 11, lin. 35-41). Other solvents include fatty acid ester and alcohols such as oleyl alcohol (pg 10, lin. 18-20). The solutions are filled

into separate containers and combined with propellants to form aerosol sprays (*Ibid.*). The formulation is applied in various manners such as absorbent tampons or transdermal patches (pg. 12, lin. 9-14). The canister would have a label disclosing the contents and concentrations of each component.

The reference discloses the TRPV1 agonists present in an amount of about 5%, yet is silent to higher concentrations. Higher concentrations of TRPV1 agonist compounds are known win the art as seen in the '112 patent.

The '112 is drawn to a topical formulation comprising capsaicin and permeation enhancing agents (abstract). The topical preparations include lotions, creams, solutions and gels comprising from 1-25% capsaicin (col. 3, lin. 34-40). The permeation enhancers include oleyl alcohol and propylene glycol (col. 4, lin. 4-29). It would have been obvious to one of ordinary skill in the art to apply the higher concentration of capsaicin as seen in the '112 patent in order to provide a reduction in irritation to the end user and to optimize the dosage.

The '000 reference is further silent to a specific removal step or kit providing this feature, however any known removal method such as rinsing the applied area would be appropriate. A specific step would have been obvious to one of ordinary skill in the art in order to restore the skin to its original state. It would have been obvious to also rinse the applied area with a removal formulation that would leave the skin in its original state or better. This can be seen in the '539 patent.

The '539 patent discloses a mild rinse/off formulation comprising antimicrobial agents that continues to protect the skin against further infection (abstract). The mildest formulation that is most gentle to the skin comprises surfactants such as polyethylene glycol in a

concentration from about 20-70% (col. 15, lin. 35-45). The liquid products can be applied to the forearm after it has been wet using a water tap from a standard basin, the formulation is applied and rinsed away in the basin (col. 21, lin. 55-col. 22, lin. 14). It would have been obvious to rinse the skin with the formulation of the '539 patent since it is mild and would also protect the skin against further bacterial infection.

Regarding the retention of the TRPV1 agonist in the skin, it is the position of the Examiner that such limitations are merely functional limitations inherent to the formulation, e.g., same compositions must have same properties. The method of the instant claims requires that a topical formulation comprising a TRPV1 agonist and a penetration enhancer in a specific surface area. The '000 patent teaches that the formulations are applied in at least this surface area in an effective method. The retention of the agonist is a function of the composition and since the compositions of the '000 and the instant claims are identical it follows that the '000 formulation must also act accordingly. It is the position of the Examiner that the formulation of the '000 would inherently remain in the skin of the desired duration in order to be fully effective.

Regarding the duration of the pain relief limitations, it is the position of the Examiner that such limitations are merely functional limitations that fall naturally from the practice of the claimed method. The prior art provides a method of delivering a TRPV1 compound to the skin in a comparable concentration, in combination with the same solvents, all combined into a similar form and applied to the same area. Since a compound and its properties cannot be separated, the practice of applying the liquid composition of the prior art comprising the same components of the instant claims will inherently provide pain relief for up to six months, depending on the pain and the individual.

With these things in mind it would have been obvious to combine the higher concentration of the capsaicin of the '112 patent into to the formulation of the '000 patent in order to provide improved comfort and reduced irritation. It would have been obvious to, after applying the topical formulation of the '000 patent, rinse the skin with the cleansing composition of the '539 patent in order to protect the skin against further infection and sooth the skin from any harsh effects of the '000 product. It would have been obvious to one of ordinary skill in the art to combine the prior art with the rationale of the result of a stable topical formulation and method of pain relief.

Response to Arguments

Applicant's arguments with respect to claims 1, 7, 9, 10, 11, 85, 86, 88-90, 93, 95, 97-105, and 122-145 have been considered but are moot in view of the new ground(s) of rejection.

The '000 patent continues to disclose a method for applying a TRPV1 agonist to the skin via the skin or mucosa comprising applying a liquid formulation comprising a TRPV1 agonist in an effective concentration similar to the instant claims, a solvent system comprising propylene glycol and an oleyl alcohol.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 85, 86, 88-90, 93, 95, and 97-103 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 16, 17, 20, 21, 24, 25, 28, 39-45, 47, 50-54 and 60-63 of copending Application No. 11/411,328. Although

the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to pharmaceutical formulations comprising a TRPV1 agonists such as capsaicin in a topical formulation such as a gel, lotion or patch. The instant claims are more specific about including a penetration enhancer; however these components would be inherent to a gel, lotion or topical formulation meant to deliver agents to the skin. For these reasons the claims would act as obviating art over another.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 8:00-5:30; every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618